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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,476	06/08/2001	Jan G. Jaworski	07148-108001	9870

26191 7590 02/26/2003

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/877,476	JAWORSKI ET AL.	
	Examin r	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 14, 17, 22 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13, 15, 16, 18-21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group VI, claims 12, 13, 15, 16, 18-21, 23 and 24 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the claims all depend from claim 1 and that it would not be an undue burden on the Examiner to search all of the inventions. Applicants further argue that restriction of claims 1-11 is improper since the dependent claims are subgroups of the dependent claim, and similarly restriction of claims 12-25 is not warranted, which regrouping is supported by the classification. This is not found persuasive because the inventions would require different areas of search and the search and examination of all the inventions would be an undue burden, and the restriction is properly made for the reasons of record set forth in the last office action.

10 The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 14, 17, 22 and 25 are withdrawn from consideration.

Claims 12, 13, 15, 16, 18-21, 23 and 24 are objected to for depending on a non-elected base claim.

15 The specification is objected to for the inclusion of a web hyperlink on page 10. Due to the problem of new matter in websites, the hyperlink must be deleted from the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

20 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 21, and claims 23 and 24 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 Claims 20 and 21 are confusing in the recitation of "a plant containing an exogenous nucleic acid", since the DNA would not be exogenous when it is in the plant.

35 U.S.C. 101 reads as follows:

10 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15 Claims 12, 13, 15, 16, 19-21, 23 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a nucleic acid encoding a polypeptide that was known from *Brassica napus*. Claims are also drawn to host cells and plants, including *B. napus* that contain said DNA. The claims read on a product of nature given the claimed nucleic acid is not isolated, and given that cells and plants containing the same DNA are naturally occurring.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 13, 15, 16, 18-21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a nucleic acid sequence that encodes a membrane anchoring polypeptide and a third polypeptide having at least 40% sequence identity to residues 15-506 of SEQ ID NO: 4. However, it is unclear what sequences would encode a protein having membrane anchoring properties, and particularly to what membrane, and the specification fails to describe what structural features are required to result in protein having the claimed activity. In addition, it is unclear what functional activity the entire polypeptide would have, given the low percentage of sequence identity of the third polypeptide, and given that the claim does not specify the functional activity for the claimed sequence. Thus, the physical and the functional characteristics of the claimed nucleic acid are uncertain. And therefore, the physical and phenotypic characteristics of cells and plants containing said nucleic acid is also uncertain.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir.

1997), where it states:

“The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . .”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

5 The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 12, 13, 15, 16, 18-21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids having polypeptides with membrane anchoring function from FAE or KCS polypeptides, as disclosed on page 10 and having the specified residues of SEQ ID NO: 12 or 14, does not reasonably provide enablement for any membrane anchoring polypeptide and any sequence having 40% identity to residues 115-506 of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

20 The specification discloses a nucleic acid encoding a polypeptide having fatty acid elongase activity. However, it is unclear what sequences would encode a protein having that activity and the specification fails to describe what structural features are required to result in protein having the claimed activity.

More specifically, identification of related sequences that will encode enzymes having a specific activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the functionality or more knowledge of the particular structural features that are required for conferring this function. Furthermore, the use of membrane anchoring polypeptides that are not disclosed or described is highly unpredictable.

Therefore, it would require undue experimentation to establish how to use the claimed sequences, given the uncertainty of the functionality of any sequences that are membrane anchoring polypeptides and have at least 40% sequence identity to residues 115-506 of SEQ ID NO: 4, as stated above; the lack of working examples of other sequences that would function in the same manner; the absence of guidance with regard to which sequences would encode a protein that would function as a fatty acid elongase; and the absence of guidance with regard to use of any other sequences; and given the breadth of the claims which encompass any nucleic acids that has membrane anchoring polypeptides and have at least 40% sequence identity to

residues 115-506 of SEQ ID NO: 4; it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

5 obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20 Claims 12, 13, 15, 16, 18-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al (WO 96/13582) taken with Clemens et al (Accession AF009563).

The claims are drawn to a nucleic acid encoding a fatty acid elongase having three polypeptide segments, and to host cells, and plants containing said nucleic acid sequence.

James et al teach a fatty acid elongase gene, and transformation of said gene into host cells, including yeast, and into plant cells and plants, including *Brassica napus* (see pages 2, 10 and 34, for example). In addition, James et al teach a *B. napus* plant, wherein said plant would inherently contain an fatty acid elongase coding sequence having a membrane anchoring polypeptide segment.

James et al do not specifically teach a nucleic with all of the limitations of claim 1.

Clemens et al teach a nucleic acid that is 97.94% identical to the claimed second and third polypeptide segments, and a polypeptide having membrane anchoring properties would be inherent in a fatty acid elongase sequence from *B. napus*.

Given the recognition of those of ordinary skill in the art of the value of transforming host cells and plants with a nucleic acid encoding a fatty acid elongase, as taught by James et al, it would have been obvious to substitute another nucleic acid encoding a fatty acid elongase, such as that taught by Clemens et al or a similar sequence having the same properties. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this

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Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

5 Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
February 24, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

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